



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DEC 26 2000

The Honorable William J. Clinton
The White House
Washington, DC 20500

Dear Mr. President:

The annual appropriations bill for the Food and Drug Administration (FDA) (P.L. 106-387), signed into law earlier this year, included a provision to allow prescription drugs to be reimported from certain countries for sale in the United States. The law requires that, prior to implementation, the Secretary of Health and Human Services demonstrate that this reimportation poses no additional risk to the public's health and safety and that it will result in a significant reduction in the cost of covered products to the American consumer.

I am writing to advise you that I cannot make the demonstration called for in the statute because of serious flaws and loopholes in the design of the new drug reimportation system. As such, I will not request the \$23 million that was conditionally appropriated for FDA implementation costs for the drug reimportation system included in the FY 2001 appropriations bill.

As you know, Administration officials worked for months with members of Congress and staff to help them design safe and workable drug reimportation legislation. Unfortunately, our most significant concerns about this proposal were not addressed. These flaws, outlined below, undermine the potential for cost savings associated with prescription drug reimportation and could pose unnecessary public health risks.

First, the provision allows drug manufacturers to deny U.S. importers legal access to the FDA approved labeling that is required for reimportation. In fact, the provision explicitly states that any labeling information provided by manufacturers may be used only for testing product authenticity. This is a major loophole that Administration officials discussed with congressional staff but was not closed in the final legislation.

Second, the drug reimportation provision fails to prevent drug manufacturers from discriminating against foreign distributors that import drugs to the U.S. While the law prevents contracts or agreements that explicitly prohibit drug importation, it does not prohibit drug manufacturers from requiring distributors to charge higher prices, limit supply, or otherwise treat U.S. importers less favorably than foreign purchasers.

Third, the reimportation system has both authorization and funding limitations. The law requires that the system end five years after it goes into effect. This "sunset" provision will likely have a chilling effect on private-sector investment in the required testing and distribution systems because of the uncertainty of long-term financial returns. In addition, the public benefits of the new system are diminished since the significant investment of taxpayer funds to establish the new safety monitoring and enforcement functions will not be offset by long-term savings to

consumers from lower priced drugs. Finally, Congress appropriated the \$23 million necessary for first year implementation costs of the program but did so without funding core and priority activities in FDA, such as enforcement of standards for internet drug purchase and post-market surveillance activities. In addition, while FDA's responsibilities last five years, its funding authorization is only for one year. Without a stable funding base, FDA will not be able to implement the new program in a way that protects the public health.

As you and I have discussed, we in the Administration and the Congress have a strong obligation to communicate clearly to the American people the shortcomings in policies that purport to offer relief from the high cost of prescription drugs. For this reason, I feel compelled to inform you that the flaws and loopholes contained in the reimportation provision make it impossible for me to demonstrate that it is safe and cost effective. As such, I cannot sanction the allocation of taxpayer dollars to implement such a system.

Mr. President, the changes to the reimportation legislation that we have proposed can and should be enacted by the Congress next year. At the same time, I know you share my view that an importation provision - no matter how well crafted - cannot be a substitute for a voluntary prescription drug benefit provided through the Medicare program. Nor is the solution a low-income, state-based prescription drug program that would exclude millions of beneficiaries and takes years to implement in all states. What is needed is a real Medicare prescription drug option that is affordable and accessible to all beneficiaries regardless of where they live. It is my strong hope that, when Congress and the next Administration evaluate the policy options before them, they will come together on this approach and, at long last, make prescription drug coverage an integral part of Medicare.

Sincerely.



Donna E. Shalala